

DOCKET JB0602

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: R. Fuerst et al

5 Serial Number: 10/735,451

Filed: 12/12/03

Examiner: MATHIEUU D. VARGOT

:Group 1732

:Phone (571) 272 1211

:FAX (703) :Date 10/18/07

Re: The Application For:

10

FABRICATION OF IMPROVED CONTACT LENS UTILIZING POLYMER ELECTROSPINNING

SUPPLEMENT TO FIRST AMENDMENT AND REPLY MAILED 09/18/06

15

Mail Stop: NON-FEE AMENDMENT

Hon. Commissioner of Patents and Trademarks

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Dear Sir:

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Josep J Bourse

(Signature of person mailing paper, Joseph Bango, Co-Inventor)



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Examiner: MATHIEU D. VARGOT

Serial Number: 10/735,451

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:Phone (571) 272-1211

:Date 08/16/07

Re: The Application For:

FABRICATION OF IMPROVED CONTACT LENS UTILIZING POLYMER ELECTROSPINNING

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Mail Stop: NON-FEE AMENDMENT Hon. Commissioner of Patents and Trademarks PO BOX 1450 ALEXANDRIA, VA 22313-1450

Dear Sir:

This correspondence is in response to the Examiner's paper, an "OFFICE COMMUNICATION" mailed 04/17/07

Re: THE FOLLOWING DECLARATION OF GARY E. WNEK

7 September 2007

DECLARATION AND STATEMENT OF GARY WNEK: RELATING TO "Simpson et al publication US No. US 2002/0090725, PUBLISHED ON July 11th 2002"

I, Dr. Gary Wnek, do hereby say and declare: This is my statement relating to my review of a prior art patent reference on which I am listed as a co-inventor, and which is cited by patent examiner Niebauer, as that reference relates to pending patent application number 10/414,796.

My qualifications for making the following declaration:

Past and Present Employment:

GARY E. WNEK

Joseph F. Toot, Jr., Professor of Engineering
Chair, Department of Macromolecular Science and Engineering
Faculty Director, The Institute for Management and Engineering (TiME)
Case Western Reserve University
Cleveland, Ohio 44106-7217
216-368-4172; gew5@case.edu

Former Positions

7/04-6/06:

Joseph F. Toot, Jr., Professor of Engineering Professor of Chemical Engineering Co-Director, The Institute for Management and Engineering (TiME) Case Western Reserve University

1/04-6/04:

Professor of Chemical Engineering
Affiliate Professor of Chemistry and Biomedical Engineering Virginia
Commonwealth University, Richmond, VA

8/96-12/03:

Professor and Founding Chair
Department of Chemical Engineering
Affiliate Professor of Chemistry and Biomedical Engineering Virginia
Commonwealth University, Richmond, VA

7/93-8/96:

Professor and Chair, Department of Chemistry Director, Polymer Science and Engineering Program Rensselaer Polytechnic Institute, Troy, NY

7/92-6/93:

Professor of Chemistry
Director, Polymer Science and Engineering Program
Director, Center for Polymer Synthesis
Rensselaer Polytechnic Institute, Troy, NY

1987-1992:

Associate Professor of Chemistry
Director, Polymer Science and Engineering Program Rensselaer Polytechnic
Institute, Troy, NY
1985-1987:

ARCO Associate Professor of Polymers Department of Materials Science and Engineering Massachusetts Institute of Technology

Cambridge, 1983-1985:

IBM Assistant Professor of Polymers

Department of Materials Science and Engineering Massachusetts Institute of Technology, Cambridge, MA

1980-1983:

Dupont Assistant Professor of Polymers

Department of Materials Science and Engineering Massachusetts Institute of Technology, Cambridge, MA

Education

B.S., Chemical Engineering, Worcester Polytechnic Institute, 1977 senior thesis advisor: Dr. Leonard B. Sand

Ph.D., Polymer Science and Engineering, University of Massachusetts, Amherst, 1980 Thesis Advisor; Dr. James C. W. Chien

Date and Place of Birth September 9, 1955; Amsterdam, NY

Publications (See Appendix for complete list)

Over 130 papers and book chapters; 18 US patents.

Awards and Honors

John W. Hyatt Award (benefit to society), Society of Plastics Engineers, 2007 Kern Faculty Fellow, Kern Entrepreneurship Education Network, 2006-07 Honorary Member, Golden Key International Honor Society, 2005-NASA Lecturer, 64th Frontiers in Chemistry Symposium, Case Western Reserve University, 2004 Sidney Negus Memorial Lecturer, Virginia Academy of Sciences, 1999

1996 Eastern New York Intellectual Property Law Association Inventor of the Year Award (for U.S. patent 5,468,574)

Union Carbide Lecturer, 44th Frontiers in Chemistry Symposium, Case Western Reserve University, 1985 Lecturer, Whitney Symposium on Science and Technology, General Electric CR&D, 1985 ARCO Career Development Award, 1985-1987

IBM Faculty Development Award, 1983-1985 Dupont Young Faculty Award, 1980-1983

Professional Societies

American Chemical Society (Divisions of Polymer Chemistry and Polymeric Materials: Science and Engineering)
American Institute of Chemical Engineers
Materials Research Society
Product Development Management Association

Professional Activities

Co-Editor, Encyclopedia of Biomaterials and Biomedical Engineering (Marcel Dekker), 2004-Councilor, ACS Division of Polymer Chemistry, 2005-2007 Board of Consulting Editors, McGraw-Hill Encyclopedia of Science and Technology and Yearbook of Science and Technology, 2002-2004 Member, Panel on Organic and Hybrid Materials, Materials Research for Defense-After-Next, National Materials Advisory Board, 200 1-2002 Scientific Advisory Board, GliaMed, Inc., Bronx, NY, 2003-Scientific Advisory Board, Bio-Track LLC, Richmond, VA, 200 1-Scientific Advisory Board, Energy Voyager Inc., Santa Barbara, CA, 2005-Associate Editor, Chemistry of Materials, 1989-1996 Editorial Board, Chemistry of Materials, 1997-2000 Editorial Board, Polymer-Plastics Technology and Engineering, 1998-Editorial Board, Progress in Polymer Science, 1993-95 Co-Founder, Dais Corp., 1993 (now Dais Analytic Corp.) Co-Founder and CSO, Aegis BioSciences LLC, 1996-Co-Founding Inventor, NanoMatrix, Inc., 2000-Co-Principal, Class Express LLC, 2004-Advisory Board, Department of Chemical Engineering, Worcester Polytechnic Institute, 1990-; Chair, 2003-

Research Interests

Polymers with unusual electrical or optical properties Ironically conducting polymers with applications in fuel cells and batteries Electro active polymers in medicine and biotechnology Electric field-mediated phenomena: electrostatic polymer processing of nanoand micro fibers and particles; morphology modulation in polymer blends; modulation of optical properties of polymers. Biomaterials for tissue engineering and regenerative medicine

New polymer-based micro fluidic platforms

Date(s) Of Review: 7 September 2007

Prior Art References: Electro processed Collagen, David Simpson et al,

US No. US 2002/0090725

I have been engaged in polymer research for nearly 30 years and with electrospinning of polymers for 9 years.

I am currently Chairman of the Department of Macromolecular Science and Engineering at Case Western Reserve University in Ohio. I was of several principal Investigators at Virginia Commonwealth University in the electrospinning, henceforth electro-processing, program at VCU which resulted in the cited patent reference US No. US 2002/0090725 to Simpson et al. I am a co-inventor on that application.

The purpose of our research and subsequently reported in the literature and documented in the cited patent reference, was to produce a biomimetic tissue scaffold suitable for, and to encourage, cellular in growth and neovascularization. Our team had no interest in and never thought about removing the charge from the sprayed fibers. The electrohydrodynamic instability cited in the Bango application does not usually present itself as a problem in the application of tissue scaffolds, although we did attempt to prepare oriented fibers through mechanical means, e.g. using a rotating drum. In our work, we had no interest in making electrospun collagen fibers optically clear. Optical clarity in the visible spectra requires mimicking the fibril diameter and mean fibril spacing exhibited by native tissue, specifically under 100 nanometers in diameter. To my knowledge, we never spun fibers under 100 nanometers. The diameter of the individual fibers in the cited Simpson et al. application was to be larger than those in the Bango et al. application.

I consider the use of AC or alternating current for mitigating spray instability the electrospray source to be novel. The need for AC voltage was neither necessary nor contemplated for the scaffolding application taught in the Simpson publication.

Ultraviolet light and/or radiation were used in the process taught in the Simpson publication to promote polymer crosslinking or fiber sterilization. Ultraviolet light was not used in the Simpson process taught in the Simpson publication to remove any charge buildup on the spun fiber.

The examiner makes reference to a corona discharge as an ion source to mitigate fiber instability. A corona is in effect a plasma, and as such over a thousand degrees F in temperature. Such high temperature can denature collagen.

Use of a plasma also produces ozone, which might further destabilize collagen. As such. I would not see a corona as being an enabling means to minimize fiber spinning instability for this application.

Finally, the examiner cites the use of the microprocessor in the spinning operation. The microprocessor was used in the process taught in Simpson to direct the angle and distance and voltage of the tip of the needle with respect to the target, depending on the desired fiber morphology and deposition required for a given application.

The microprocessor commanded a fixed voltage once our process was activated.

The microprocessor in the Simpson process was not used to deliver an AC rather than DC potential to the electrospinning source and target. The mats produced were contemplated to be as structurally sound as we could make. We did not contemplate making an optically clear mat.

As a result of not contemplating the need to make an optically clear mat, we were never faced with the problems associated making nanofibers and forming a fiber matrix that would be optically clear. We were aware of hydrodynamic instability but were typically not concerned with mitigating it as we were making fibers with a larger diameter than those characterized in the subject application, and the need for formatting a matrix aperture having optical clarity was not an area of investigation that we thought of, or that we intended to pursue.

I hereby declare that all statements made herein of my own know edge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that statements, are covered under 18 U.S.C. 1001 and that such false statements may jeopardize the validity of the application or any patent issued thereon.

Given Name (first and middle): Gary Edmund

Family Name or Surname/Wnek

Inventors Signature:

Date: September 7, 2007

Residence City: Cleveland

State: Ohio

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Country: USA

Phone Number (Day Office): 216-368-4172

APPENDIX:

Authored and Co-Authored Publications (130)

E. Karasz, J. C. W. Chien, R. Galkiewicz, G. E. Wnek, A. J. Heeger and A. G. MacDiarmid, "Nascent Morphology of Polyacetylene," Nature, 282, 286 (1979). E. Wnek, J. C. W. Chien, F. E. Karasz, M. A. Druy, A. G. MacDiarmid, Y. W. Park and A. J. Heeger, "Variable Density Conducting Polymers: Conductivity and Thermopower Studies of a New Form of Polyacetylene, (CH)x," J. Polym. Sci. Polym. Lett. Ed., 17, 779 (1979).

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- J. C. W. Chien, F. E. Karasz and G. E. Wnek, "Soliton Formation and Cis-Trans Isomerization in Polyacetylene," Nature, 285, 391 (1980).
- A. Feldblum, Y. W. Park, A. J. Heeger, A. G. MacDiarmid, G. E. Wnek, F. E. Karasz and J. C. W. Chien, "Microwave Properties of Low-Density Polyacetylene," J. Polym. Sci. Polym. Phys. Ed., 19, 173 (1981).
- J. C. W. Chien, G. E. Wnek, F. E. Karasz and J. A. Hirsch, "Electrically Conducting Acetylene/Methylacetylene Copolymers Synthesis and Properties," Macromolecules, 14, 479 (1981).
- G. E. Wnek, J. Capistran, J. C. W. Chien, L. C. Dickinson, R. Gable, R. Gooding, K. Gourley, F. E. Karasz, C. P. Lillya and K. D. Yao, "Studies in Conducting Polymers," in Conductive Polymers, Polym. Sci. & Tech. Ser., Vol. 15, R. B. Seymour, ed., Plenum, 183 (1981).
- J. C. W. Chien, G. E. Wnek, F. E. Karasz, J. M. Warakomski, L. C. Dickinson, A. J. Heeger and A. G. MacDiarmid, "Electron Paramagnetic Resonance Saturation Characteristics of Pristine and Doped Polyacetylenes," Macromolecules, 15, 614 (1982).
- M. E. Galvin and G. E. Wnek, "Electrically Conductive Polymer Composites: Polymerization of Acetylene in Polyethylene" Polym. Comm., 23, 795 (1982).

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- M. E. Galvin and G. E. Wnek, "Characterization of Polyacetylene/Low Density Polyethylene Composites Prepared by In-Situ Polymerization," J. Polym. Sci. Polym. Chem. Ed., 21, 2727 (1983).
- M. E. Galvin and G. E. Wnek, "Towards the Synthesis of Electroactive Block Copolymers via Anionic-to-Ziegler-Natta Transformation Reactions," Polym. Prepr., 24(2), 14 (1983).
- L. R. Dalton, H. Thomann, H. Kim, A. Morrobel-Sosa, C. Chiu, M. E. Galvin, G. E. Wnek, Y. Tomkiewicz, N. S. Shiren, B. Robinson and A. L. Kwiram, "Characterization of the Wavefunction and Dynamics of the Soliton in Polyacetylene and Composites of Polyacetylene/ Polyethylene," J. Appl. Phys., 54 (10), 5583 (1983).
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- G. Venugopal, S. Krause and G. E. Wnek, "The Effects of Electric Fields on Polymer Blend Morphologies," Polym. Prepr., 31(1), 377 (1990).
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- "Production of Microfibers by Electrospinning," Philip Morris Technical Center, Richmond, VA, February 13, 2001
- "Electrospinning of Biomaterials," S. K. Tripathy Memorial Symposium, U. Massachusetts Lowell, February 16, 2001.
- "Electric Field-Mediated Processing of Biomaterials: Toward Nanostructured Biomimetic Systems," SPIE Annual Meeting, Newport Beach, CA, March 8, 2001.

- "Thinking Small at the Engineering/Medical Interface," Molecular Cell Biology and Biotechnology Seminar Series, Virginia Tech, Blacksburg, April 27, 2001. "Small Thinking About Old Polymers at the Medicine/Engineering Interface," Program in Polymer Science & Technology seminar series, MIT, Cambridge, MA, May 16, 2001.
- "Electrospinning of Biomaterials," Fiber Society Meeting, Raleigh, May 23, 2001.
 "Sulfonated Styrene-Based Proton Exchange Membranes," Session on Macromolecular Assemblies for Electronic and Photonic Applications, ACS National Meeting, Chicago, August 28, 2001.
- "Small Thinking About Old Polymers at the Medicine/Engineering Interface," Chemical Engineering Seminar, Worcester Polytechnic Institute, Worcester, MA. October 18, 2001.
- "Electroactive Polymers in Medicine and Energy Conversion," Search for Electroactive Materials (SEAM) meeting, Polytechnic University, Brooklyn, Dec. 1, 2001
- "Electrostatic Processing of Polymers," James McGrath Applied Polymer Science Award Symposium, Orlando ACS Meeting, April 9, 2002.
- "Small Thinking About Old Polymers at the Medicine/Engineering Interface," Department of Chemical Engineering, University of Colorado, Boulder, September 10, 2002.
- "Nanoscale Delivery, Surgery and Implant Devices," 2002Virginia Biotechnology Summit and Governor's Conference on Technology Transfer and University Research, Herndon, VA, October 15, 2002.
- "Thinking Small About Old Polymers at the Medicine/Engineering Interface," Golden Gate Polymer Forum, Mountain View, CA, November 12, 2002. "Thinking Small About Old Polymers at the Medicine/Engineering Interface," ACS Workshop on Polymers in Medicine and Biology, Sonoma, CA, November 16, 2002.
- "Toward New Synthesis and Processing Approaches for PEM Components," ACS Conference on Advances in Materials for Proton Exchange Membrane Fuel Cell Systems, Asilomar, CA, February 24, 2003.
- "Polymer Micro- and Nanofibers and Applications to Dentistry," School of Dentistry, VCU, Richmond, February 12, 2003.
- "Thinking Small About Old Polymers at the Medicine/Engineering Interface," Alza Corp., Palo Alto, CA, February 27, 2003.
- "Polymer Micro- and Nanofibers by Electrospinning," Department of Chemical Engineering, Case Western Reserve University, Cleveland, OH, March 6, 2003. "Polymer Micro- and Nanofibers by Electrospinning," Department of Chemical Engineering, Rensselaer Polytechnic Institute, Troy, NY, March 19, 2003. "Polymer Micro- and Nanofibers by Electrospinning," Department of Chemical Engineering, Georgia Institute of Technology, Atlanta, June 19, 2003. "Electrospinning of Biomimicking Tissue Engineering Scaffolds," Gordon Research Conference on Biomaterials: Biocompatibility/Tissue Engineering, Holderness School, Plymouth, NH, July 21, 2003.

- <u>"Polymers in Tissue Engineering and Fuel Cells: Examples of Entrepreneurship in Engineering."</u> Case Western Reserve University, Cleveland, OH, December 4, 2003.
- "Electrostatic Polymer Processing: Applications to Biomaterials and Electrochemical Devices," S. K. Tripathy Annual Memorial Symposium, UMass Lowell, Dec. 5, 2003.
- "Electrostatic Polymer Processing: Applications to Biomaterials and Electrochemical Devices," University of Florida, Dept. of Chemical Engineering, January 7, 2004.
- "Opportunities and Engineering Challenges for PEM Fuel Cells," AIChE-ASME joint local section meeting, Richmond, VA, January 22, 2004.
- "Electrostatic Polymer Processing: Applications to Biomaterials and Electrochemical Devices," Yale University, Dept. of Mechanical Engineering, March 24, 2004.
- "Polymer Nanofibers by Electrospinning and Applications in Medicine," Symposium on Nanotechnology and Education, ACS Meeting, Anaheim, CA, March 29, 2004.
- "Electrostatic Polymer Processing: Applications to Biomaterials and Electrochemical Devices," Dept. of Polymer Engineering, University of Akron, April 9, 2004.
- "Electrostatic Polymer Processing of PEMFC Components," Gordon Research Conference on Fuel Cells, Roger Williams University, Bristol, RI, July 29, 2004. "Polymer Engineering for Energy Conversion Technologies," Frontiers in Chemistry Series, Case Western Reserve University, October 28, 2004.
- "Nanornaterials for Fuel Cells," PolymerOhio Emerging Technology Forum, Case Western Reserve University, November 17, 2004.
- "Electrostatic Polymer Processing Applied to PEMFC Fabrication," ACS workshop on New Advances in Proton Exchange Membrane Fuel Cells, Asilomar, CA, February 23, 2005.
- "Medical Applications of Electrostatic Polymer Processing," Guidant Corporation, Santa Clara, CA, February 23, 2005.
- "Polymer Engineering for Energy Conversion Technologies," Golden Gate Polymer Forum, Mountain View, CA, February 23, 2005.
- "Structure-Property Relationships in Biopolymers," ACS short course on Polymers in Medicine, Richmond, VA, June 8, 2005.
- "Electrostatic Polymer Processing Applied to PEMFC Fabrication," 1st Symposium on Manufacturing of MEAs for Hydrogen Applications, Dayton, Ohio, August 10, 2005.
- "Nanomaterials with Applications to Medicine and Energy," Materials Science and Engineering Alan Lawley Seminar, Drexel University, Philadelphia, November 1, 2005.
- "Electrostatic Polymer Processing Applied to PEMFC Fabrication," Pacific Polymer Conference, Maui, HI, December 12, 2005.
- "Nanomaterials with Applications to Medicine and Energy," Materials Engineering colloquium, Purdue University, W. Lafayette, IN, March 3, 2006.

"Applying TRIZ Methodology to Innovation Strategy," Ohio Polymer Summit, Columbus, May 23, 2006 (with Zion Bar-El).

"Nanomaterials with Applications to Medicine and Energy," Dow Discussion Group on Interface Science, Dow Chemical Co., Midland, MI, May 24, 2006. "Electrospinning of Polymers: Fundamentals and Medical Applications," International Conference on Polymer Chemistry, Dalian, China, June 10, 2006. "Electrospinning of Polymers: Fundamentals and Medical Applications," Mini-Symposium on Functional Polymers and Nanostructured Materials for Biotechnology and Medicine, Shanghai Jiao Tong University, Shanghai, China, June 12, 2006.

Short Courses Taught

"Practical Polymer Science," Denison Manufacturing Co., Framingham, MA, February-March 1981 and May 1986.

<u>"Electrical Properties of Polymers,"</u> one-week summer course, MIT, Cambridge, MA, 1985-1989.

"Electrically Conducting Polymers," ACS Satellite TV Course, Washington, DC, March 16, 1990 (with P. D. Calvert and D. J. Meier).

"Polymer Chemistry," three-day short course for college faculty, Temple University, Philadelphia, March 29-31, 1990.

"Chemistry and Materials Science," NSF Chautauqua Course for College Teachers, U. of Pittsburgh, June 16-18, 1994.

"Chemistry and Materials Science," NSF-UFE Short Course, Bucknell U., Lewisburg, PA, August 4-6, 1994.

"Polymer Chemistry for University Faculty," NSF-supported, 3-week summer course at RPI (G. E. Wnek, P.I., with S. Krause and J. A. Moore), 1989, 1991, 1993 and 1996.

<u>"Essentials of Polymer Chemistry,"</u> ACS Satellite TV Course, Washington, DC, March 23 and 25, 1998 (with J. E. McGrath, K. J. Wynne and D. A. Tirrell; organized by G. E. Wnek).

"Polymers in Medicine: Principles and Practice," ACS short course held at VCU, June 2003; organized by K. J. Wynne, co-organized by G. E. Wnek.

<u>"Polymers and Bio-Polymers in Medicine,"</u> Golden Gate Polymer Forum Short Course, May 5-7, 2006 (co-organized co-taught with Allan Hoffman and Stuart Williams).

End of Appendix